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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,390	03/05/2002	Michael Graner	8449-181-999	8714
20583	7590	01/09/2004	EXAMINER	
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			WEBER, JON P	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,390	GRANER ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>06/18/02</u> . | 6) <input type="checkbox"/> Other: . |

Status of the Claims

Claims 1-20 have been presented for examination.

Specification

The disclosure is objected to because of the following informalities:

The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. Apps. 1931). Several detergents, such as TRITON, and IGEPAL are recited at various locations.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1-b and claim 10-i, recite "collecting one or more fractions" which is confusing because it is not clear if the one or more fractions are pooled or kept separate. If kept separate, the fractions could correspond to pure single chaperone proteins. However, if the fractions containing the chaperones are intended to be pooled, the result is a mixture of chaperones. From reading the disclosure it would appear that the latter is the intended meaning and the claims have been examined with respect to the prior art with this meaning. Consistent with this interpretation is independent product by process claim 11.

Claims 9-10 and 17 recite Trademarked materials TRITON and IGEPAL. "To describe physical or other properties of material by mere use of **trademark** is objectionable since it has tendency to make trademark descriptive of product rather than leaving trademark to serve its traditional purpose which is to identify product's source of origin". The issue involved the use of the Trademark **Hypalon** in the claims which Appellants have argued to be within the guidelines of M.P.E.P. 608.01 (v) if the meaning of the trademark is well known and satisfactorily defined in the literature. Copies of articles were submitted. No rejection was made based on first paragraph of 35 USC 112 which was correct but the rejection was on second paragraph which was considered to be correct by the board. "A patent applicant has an obligation that is imposed by 35 USC 112, second paragraph, to employ claim terminology which is definitive of what the public is not free to use, and use of a trademark in the manner employed by appellant has resulted in claims which fail to meet this obligation in our opinion.: see *Ex parte Simpson and Roberts* 218 USPQ 1020.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Graner et al. (Nov 2000).

Graner et al. (Nov 2000) clearly disclose exactly the same process and product as instantly claimed (Materials and Methods).

Claims 1, 3, 11 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Katsanis et al. (2000). This rejection is under this portion of the statute because of evidence that the meeting corresponding to this abstract took place in late January to early February 2000.

Katsanis et al. (2000) clearly disclose the same process and product as instantly claimed. Some of the details of the procedure are not available in the abstract provided herein. Nevertheless, the rejection is based in part on inherency. Since the pIs of the various chaperones were known at the time of the claimed invention, the disclosed FS-IEF would have inherently been performed using fractions in the claimed range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsanis et al. (2000) and Graner et al. (Nov 2000) in view of Graner et al. (Mar 2000), Lucietto et al. (1997), and Bio-Rad Tech Notes Summaries.

The teachings of Katsanis et al. (2000) and Graner et al. (Nov 2000) have been discussed above. Katsanis et al. (2000) lacks all of the details of the procedure.

Graner et al. (Mar 2000) combines purified chaperones into a mixture with improved immunoprotective activity.

Lucietto et al. (1997) discloses that chaperonin-10 from *M. tuberculosis* can be readily purified using preparative IEF as a first step.

Bio Rad Tech Notes Summaries discloses that it was known in the art to use detergents such as n-octylglucoside and CHAPS and/or denaturants such as 3-6 M urea as aids in purifying proteins by FS-IEF.

A person of ordinary skill in the art at the time the invention was made would have been motivated to use detergents and denaturants such as urea in an IEF method of purifying chaperones because IEF has been shown by Katsanis et al. (2000), Graner et al. (Nov 2000), Graner et al. (Mar 2000) and Lucietto et al. (1997) to be good to purify chaperones and these additives have been shown by Bio Rad Tech Notes Summaries to facilitate protein purification.

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Partial purification so as to obtain complex mixtures of chaperones is suggested by the advantageous combination obtained by Graner et al. (Mar 2000).

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to purify complex mixtures of chaperones by FS-IEF.

Other references cited by examiner but not relied upon are cited to establish the state of the art.

Zeng et al. (2003) discloses the instant invention, but is not prior art.

Joachimiak et al. (1997), Salvucci et al. (2000), Blennow et al. (1995), Eriksson et al. (1999), Large et al. (2002), and Quaite-Randall et al. (1999) each show purification of chaperones, but to high purity or even homogeneity and none using FS-IEF.

Minto. et al. (1998), Atkins et al. (1994), and Jethmalani et al. (1997) all show the partial purification of chaperone proteins by IEF, but none of these show mixtures of chaperones or FS-IEF.

Bier (US 4,588,492) discloses the FS-IEF apparatus, while Ivory et al. (US 5,298,143) disclose an improved FS-IEF apparatus.

Nieves et al. (1998), Osuji et al. (1999), and Shang et al. (2003) each disclose using FS-IEF to purify proteins from complex mixtures.

No claims are allowed.

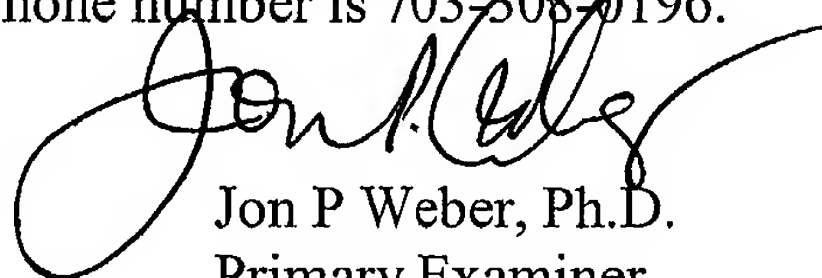
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015.

The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.

Primary Examiner

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JPW

7 January 2004